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Letter to the editor

PRP therapy classification



Dear Editor,

Last year, a new act, the Act on the Safety of Regenerative Medicine has been issued [1]. This Act covers all kinds of medical technologies using processed cells whose safety and efficacy have not yet been established. At present, it is assumed that the Act will apply to not only clinical trials performed by academia but also cell therapies administered in daily practice using processed cells in general, including cancer therapies with immune cells and so-called stem cell therapies for cosmetic purposes. Medical procedures of established safety and efficacy, such as widely performed organ transplantations, are excluded from the scope of this Act. Next, based on the concept of a risk-based approach, these medical technologies are categorized into 3 classes depending on their anticipated potential risk to human health, and the safety of individual technologies in each class is subject to review through the defined procedures. The Ministry of Health, Labour and Welfare (MHLW) showed their opinion that platelet rich plasma (PRP) injection is within the scope of this act in a Q&A issued on December 21 (2014). Recently, some clinicians and researchers expressed their objection against this decision. However, we support this decision since the safety and efficacy of PRP injection are not established yet, to our best knowledge, according to the outcomes of human clinical studies [2]. In addition, relevant non clinical studies have

not been performed. We believe that this treatment is still at a stage of experimental research, and not well established. We would like to hear candid opinions from the members of the society on this issue.

References

- [1] Hara Akinori, Sato Daisaku, Sahara Yasuyuki. New Governmental Regulatory System for stem cell-based therapies in Japan. *Ther Innovation Regul Sci* 2014;48:681–8.
- [2] Vos Robert-Jan de, Windt Johann, Weir Adam. Strong evidence against platelet-rich plasma injections for chronic lateral epicondylar tendinopathy: a systematic review. *Br J Sports Med* 2014;48:952–6.

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